CHAPTER 3
CLINICAL LABORATORIES
[Prior to 7/29/87, Health Department[470]]

641—3.1(140,596) Approved prenatal blood testing laboratories. The Iowa department of public health approves the following laboratories for the purpose of performing serologic tests in accordance with prenatal requirements:

3.1(1) The State Hygienic Laboratory at Iowa City, Iowa.

3.1(2) Laboratories of all state and territorial health departments.

3.1(3) Laboratories of the United States Public Health Service and Army, Navy and Air Force.

3.1(4) The health department laboratories of New York City and the District of Columbia.

3.1(5) The official laboratories of the provincial health departments in Canada.

3.1(6) Those private and other governmental laboratories performing serologic tests within the state of Iowa which meet the standards established for this purpose by the Iowa department of public health. A list of the approved private and other governmental laboratories is available upon request to the Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

This rule is intended to implement Iowa Code sections 140.11 and 596.3.

641—3.2(140,596) Report of results by laboratory. Any person who is in charge of a public, private, or hospital clinical laboratory shall report to the Iowa department of public health on forms prescribed by the department as required by Iowa Code section 140.5 within 24 hours the test findings or results obtained in the examination of all specimens which yield evidence of or are reactive for syphilis, gonorrhea, chancroid, granuloma inguinale or lymphogranuloma venereum.

This rule is intended to implement Iowa Code sections 140.5 and 140.7.

641—3.3(135,139) Laboratory findings of occupational or environmental illness. Any person who is in charge of a public, private, or hospital clinical laboratory shall report to the Iowa department of public health as required by Iowa Code section 139.35, test findings which yield evidence of or are reactive for a reportable poisoning, or a reportable occupationally related respiratory illness from a toxic agent or a reportable illness from a toxic agent.

641—3.4(135,139) Clinical laboratory. A clinical laboratory is any laboratory performing analyses on specimens taken from the body of a person in order to assess that person's health status.

641—3.5(135,139) Reportable laboratory findings. For those reportable conditions described in rule 641—3.3(135,139), the following subrules describe the values or criteria which require clinical laboratories to report to the Iowa department of public health. For all reportable findings listed, laboratories shall specify the analytic method and quality control measures used, as well as the values found.

3.5(1) *Heavy metal poisonings.*

a. Lead poisoning. All analytical values for blood lead analysis shall be reported to the department. Analytical values less than 10 micrograms per deciliter (μg/dL) may be reported as less than 10 micrograms per deciliter (μg/dL) rather than as the actual value. In addition to the analytical value, the following information shall be reported to the department: the date of sample collection, whether the sample is a capillary or venous blood sample, the date of birth and the address of the patient, the name and address of the patient's physician, analytical method used for the analysis, lower quantitation limit of the analytical method, and the quality assurance/quality control values associated with the analysis.

b. Mercury poisonings. Blood mercury values equal to or greater than 2.8 mcg/dL. Urine mercury values equal to or greater than 20 mcg/L.

c. Arsenic poisonings. Blood arsenic values equal to or greater than .07 mcg/mL. Urine arsenic values equal to or greater than 100 mcg/L. Twenty-four hour urinary arsenic excretion values equal to or greater than .02 mg/day.

d. Cadmium poisonings. Blood cadmium values equal to or greater than 5 mcg/L. Urine cadmium values equal to or greater than 10 mcg/L.

3.5(2) *Pesticide poisonings.*

a. Organophosphate and carbamate cholinesterase inhibiting pesticides. In using a given analytic method to measure cholinesterase inhibition, measurement techniques often vary among laboratories. For this reason, when a depressed cholinesterase value is found, in addition to reporting the items specified in rule 641—3.5(135,139), each laboratory shall provide to the Iowa department of public health evidence of the rational bases upon which the laboratory identified the reported value as depressed. For example, for nonautomated analytic methods, a laboratory may judge that a cholinesterase value is depressed on the basis of the value falling below two standard deviations from the mean value for tests completed by that laboratory on the general unexposed population. For automated methods, such as automated spectrophotometry, for which there are built-in quality control procedures and appropriate literature for determining normality, the laboratory should judge a value as depressed on the basis of such appropriate literature.

In all instances, clinical laboratories shall report any test finding which shows a 25 percent depression in red blood cell, plasma or whole blood cholinesterase from preexposure levels.

b. Other pesticide poisonings. Any herbicide, organochlorine insecticide or metabolite thereof in a clinical specimen taken from a person with a history of overexposure to such pesticides within the 48 hours previous to collection of the specimen. If a laboratory has no information regarding the exposure history of a person, a report of a positive test finding for a herbicide, organochlorine insecticide or metabolite thereof is not required, but is encouraged to be reported if the levels found are consistent with overexposure.

c. Nitrate poisonings. Blood analyses showing greater than 5 percent of total hemoglobin present as methemoglobin.

3.5(3) *Toxic hepatitis.* In cases where a laboratory has been made aware of a prolonged or possible overexposure to carbon tetrachloride, tetrachloroethane, trichloroethylene, phosphorus, TNT, chloronapthalenes, methylenedianilines, cresol or ethylene dibromide and any abnormal liver tissue biopsy findings which would be attributable to such exposure. If a laboratory has no information on the exposure history of a person, but that person's liver biopsy findings are consistent with exposure to these chemicals, then a laboratory is encouraged, but not required, to report such findings.

3.5(4) *Noninfectious respiratory illnesses.* Any biopsy of lung tissue indicating prolonged exposure or overexposure to asbestos, silica, silicates, aluminum, graphite, bauxite, beryllium, cotton dust or other textile material, or coal dust.

These rules implement Iowa Code sections 135.11(20), 135.11(21), 139.1(3), 139.2 and 139.35.

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